IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Irvin, et al.
Appl. No.:	09/865,159
Filed:	May 24, 2001
Title:	PSEUDOMONAS TREATMENT COMPOSITION AND METHOD
Art Unit:	1645
Examiner:	J. Graser
Docket No.:	113190-064

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY FIRST CLASS MAIL UNDER 37 CFR 1.8

Sir:

I hereby certify that the following documents relating to the above-identified application:

1. Request for Continued Examination Transmittal (duplicate);
2. Petition for Extension of Time (duplicate);
3. Response to Office Action (3 pgs.);
4. Information Disclosure Statement;
5. PTO Form 1449;
6. One Reference;
7. Check in the amount of $840.00; and
8. Return Receipt Postcard.

are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to:

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on May 19, 2003.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

Robert J. Buccieri
Name of Person Mailing Correspondence

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Irvin et al.
Appl. No.: 09/865,159
Conf. No.: 3428
Filed: May 24, 2001
Title: PSEUDOMONAS TREATMENT COMPOSITION AND METHOD
Art Unit: 1645
Examiner: J. Graser
Docket No.: 113190-64

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Sir:

This Response is submitted in response to the Office Action dated November 18, 2002.

REMARKS

In the Office Action, Claim 20 is rejected under 35 U.S.C. §112, first paragraph. The Patent Office asserts that the claimed invention with respect to SEQ ID Nos: 4, 8 or 10 is allowable. With respect to SEQ ID No: 6, however, the Patent Office questions as to whether Applicants were in possession of same as amended at the time of filing and thus in compliance with 35 U.S.C. §112. Applicants believe that this rejection is improper for at least the reasons set forth below.

At the outset, the primary issue with respect to the rejection is whether the amendments made to the sequence listings and corresponding figures in Applicants previously-submitted Amendment (filed on August 12, 2002) added new matter. For example, Applicants amended SEQ ID No: 6 to correct the amino acid residue "Ser" with "Cys" at position 120. Applicants believe that this amendment did not add new matter and thus should be entered and examined.

SEQ ID No: 6 represents a polypeptide sequence of a modified pilin peptide pursuant to an embodiment of the claimed invention. This sequence is a truncated pilin peptide derived from the PAO strain. As further illustrated in Figure 1C, SEQ ID No: 5 represents the corresponding polynucleotide sequence. See, Specification, pages 7 and 15. One of the advantages of the present invention is to prevent self-assembly, i.e., oligomerization, by modifying the N terminus

of the protein to prevent alpha helix formation thereby producing a pilin peptide in monomeric or dimeric form that can be effective to treat or prevent infection by *Pseudomonas aeruginosa*. See, Specification, page 6, lines 11-15.

The N-terminal portion can be modified by deletion (i.e., truncation), substitution or addition of amino acid residues effective to produce a non-self-assembling peptide that can be determined from known physical interactions that determine the properties of proteins, and from the conformational properties of polypeptide chains. In particular, modifications that affect the ability of the N-terminal portion to disrupt alpha-helix formation in the first N-terminal 30 amino acid region of the protein are generally considered to be pertinent. Introduction of Pro residues, in particular, in this segment of the protein can significantly disrupt the alpha-helix formation, but other residues that tend to destabilize alpha-helices can include, for example, groups of Gly, His or Asn. For example, a string of continuous Gly, His, or Asn residues, e.g., 3-5 residue string, can effectively prevent alpha helix formation, as can periodic Pro residues, e.g., every 5-7 residues. See, Specification, page 6, lines 23-33.

Fig. 1C illustrates an exemplary coding sequence for a modified pilin peptide with a truncated N-terminal region derived from the PAO strain as defined by SEQ ID Nos: 5 and 6 as discussed above according to an embodiment of the present invention. See, Specification, page 8, lines 4-11. However, Applicants' amendment to SEQ ID No: 6 as illustrated in Fig. 1C is directed to the C-terminal region of the PAO pilin peptide. As previously discussed, the amendment seeks to correct a single amino acid residue "Ser" with "Cys" at position 120. Clearly, one skilled in the art would understand that the C-terminal region of the claimed PAO pilin peptide as defined by SEQ ID No: 6 would remain intact and thus not modified as the N-terminal portion as supported in the Specification and discussed above.

Further, the C-terminal region of the PAO pilin peptide was well-documented and known in the art at the time of the present invention. For example, the C-terminal region of the PAO pilin peptide is illustrated in Figure 8 as disclosed in U.S. Patent No. 5,468,484 ("'484"), a copy of which is disclosed in an Information Disclosure Statement enclosed herewith. In general, the C-terminal region includes two Cys and intervening amino acid residues representative of the *Pseudomonas aeruginosa* strain (e.g., PAO) from which the peptide is derived. Typically, the C-terminal region has a length that varies between 14 and 19 amino acid residues including the two Cys residues. See, '484 Patent, col. 3, lines 40-62. Indeed, one of the inventors of the '484

Patent is also named as an inventor with respect to the above-referenced patent application. In view of same, one skilled in the art would recognize that SEQ ID No: 6 and the other previously-submitted amendments discussed above were clearly within the possession and knowledge of the inventors at the time the above-referenced application was filed. Therefore, Applicants, again, assert that the previously-submitted amendments did not add new matter, and thus are in compliance with 35 U.S.C. §112.

Accordingly, Applicants respectfully request that the rejection of Claim 20 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Thomas C. Basso
Reg. No. 46,541
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4310

Dated: May 19, 2003